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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,213	06/22/2000	Matheus Hubertus Maria Noteborn	LEBV.004.01U	6984

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/403,213

Applicant(s)

NOTEBORN ET AL.

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-16,22,25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2 and 4-16 is/are allowed.
- 6) ☒ Claim(s) 22 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/16/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

**Non-Final Rejection**

Claims 1, 2, 4-16, 22, and 25 are pending examination.

Applicants' traversal, the amendment to the specification, the amendment to claims 1, 2, 4, 5, 6, 7, 22, and 25 and the cancellation of claims 3, 17-21, 23, 24, 26, and 27 in paper no. 26 filed on 6/30/03 is acknowledged and considered.

***Priority***

The claim to "application 08/454,121 filed on 11/30/95 being a CIP of application no. 08/482,161" is incorrect because '121 was filed 5 months **after** the application '161. Thus, it is not apparent how application '161 is related to the list of applications set forth under 08/454,121. Clarification is requested.

***Claim Objections***

Claims 22 and 25 are objected to because of the following informalities: Claims 22 and 25 are grammatically incorrect. Suggest amending the claims to read

-- A method for inducing apoptosis in a mammalian tumor by directly administering to a tumor of a mammal the gene delivery vehicle of claim 1 --.

-- A method for inducing apoptosis in a mammalian tumor by directly administering to a tumor of a mammal the gene delivery vehicle of claim 6 --.

Appropriate correction is required.

Art Unit: 1635

***Claim Rejections - 35 USC § 101***

Applicant's arguments, see paper no. 26, filed 6/30/03, with respect to 101 rejection have been fully considered and are persuasive. The rejection of claims 1, 4, 6, 8, 12 and 13 has been withdrawn because of the amendment to the claims.

***Claim Rejections - 35 USC § 112***

Applicant's arguments, see paper no. 26, filed 6/30/03, with respect to 112 first paragraph rejection have been fully considered and are persuasive. The rejection of claims 22 and 25 has been withdrawn because of the amendment to the claims.

***Claim Rejections - 35 USC § 102***

Applicant's arguments, see paper no. 26, filed 6/30/03, with respect to 102 rejection as anticipated by Noteborn have been fully considered and are persuasive. The rejection of claims 1, 4, 6, 8, 12-14, 22, 23, 25, and 26 has been withdrawn because of the amendment to the claims.

Applicant's arguments, see paper no. 26, filed 6/30/03, with respect to 102 rejection as anticipated by Yuasa have been fully considered and are persuasive. The rejection of claims 1, 4, 6, 8, and 12 has been withdrawn because of the amendment to the claims.

***Double Patenting***

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010

Art Unit: 1635

(Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22 and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,472,142 in view of Chao et al., *Biochem J.*, Vol. 286, part 2, pages 555-9, 1992.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim from '142 is directed to a method of inducing apoptosis in cells that express Bip/GRP78, said method comprising: providing to said cells a nucleotide sequence that codes for a protein that induces apoptosis, wherein said protein is apoptin (VP3). Patent '142 does not explicitly claim that tumor cells express Bip/GRP78, however, Chao teaches that tumor cells express Bip/Grp78 (page 555). Thus, the claims are unpatentable over '142 in view of Chao.

Applicant's arguments with respect to claims 22 and 25 have been considered but are moot in view of the new ground(s) of rejection.

Claims 22 and 25 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,981,502.

Although the conflicting claims are not identical, they are not patentably distinct from each other

Art Unit: 1635

because the claims from '502 are directed to a method of effecting apoptosis in tumor cells, said method comprising: providing to said tumor cells a nucleotide sequence derived from a chicken anemia virus genome that codes for a protein thereof that induces apoptosis, wherein said protein is VP2 or VP3. In addition, one skilled in the art understands that naked DNA is considered a gene delivery vehicle.

Applicants offer to file a terminal disclaimer for claims 22 and 25 in regard to US Patent No. 5,981,502.

However, the rejection will not be withdrawn until the terminal disclaimer is filed.

Claims 22 and 25 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-29, 31-33 and, 37-41 of U.S. Patent No. 6,162,461. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims from '461 are directed to a method of inducing apoptosis in tumor cell, said method comprising: transfecting said cell with an expression vector encoding one or both of a polypeptide depicted in Fig 3. or Fig 2.

To speed prosecution, applicants offer to file a terminal disclaimer for claim 22 and 25 in regard to US Patent No. 6,162,461.

However, the rejection will not be withdrawn until the terminal disclaimer is filed.

### ***Conclusion***

Claims 1, 2, and 4-16 are in condition for allowance because the claims are free of the prior art of record.

Art Unit: 1635

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635



SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER